

CRYO1 CRYO-ABLATION PROBE 510(k) SUMMARY

General Information

Classification	Class II	MAR - 2 2009
Trade Name	Cryo1 cryo-ablation probe	
Manufacturer	AtriCure, Inc 6033 Schumacher Park Dr West Chester, OH 45069	
Contact	James L. Lucky VP of Quality Assurance and Regulatory Affairs	

Indications for Use

The Cryo1 cryo-ablation probe is a sterile, single use device intended for use in the cryosurgical treatment of cardiac arrhythmias. The probe freezes target tissues, creating an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.

Predicate Devices

The predicate devices for the Cryo1 cryo-ablation probe are the frigitronics CCS-200 Cardiac Cryosurgical System 3011 Maze Linear Probe (K811390), the Heartport Maze System (K970496) and the CryoCath SurgiFrost Cryosurgical 10cm Device (K053436).

Device Description

The Cryo1 cryo-ablation probe is a sterile, single use, cryosurgical device to be used in conjunction with the frigitronics CCS-200 Cardiac Cryosurgical Console to freeze target tissue, blocking the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

Materials

All materials used in the manufacture of the Cryo1 cryo-ablation probe are suitable for this use and have been used in numerous previously cleared products. Testing was conducted in accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

Summary of Substantial Equivalence

The Cryo1 cryo-ablation probe is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Atricure Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

MAR - 2 2009

Re: K082074

Trade/Device Name: Cryo1 cryo-ablation probe
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II (two)
Product Code: GEH
Dated: February 12, 2009
Received: February 13, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act.

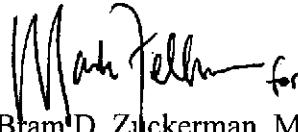
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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K082074

Device Name: Cryo1 cryo-ablation probe

Indications for Use:

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Prescription Use X
(Part 21 CRF 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CRF 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082074